NASCIC
SCI RESEARCH
ADVOCACY COURSE

Module 3 – Addressing Historical Challenges in SCI Research

Challenges Participating in SCI Clinical Trials and How Research Advocates can Help

Clinical trials are designed to specific inclusion and exclusion criteria which narrows the potential candidates for participation.

One challenge in SCI trials in meeting the enrollment requirements as well as retaining the participants who join the study.

A key factor is designing a clinical trial to facilitate participation and to ease the barriers for those clinical trial participants.

In a multi-national study conducted by Anderson, Cowan & Horsewell, they identified universal facilitators to encourage people with SCI to participate in a clinical trial as well as barriers that hinder participation.

Some of the main barriers that were identified are:

- possible decline in functionality
- possible side effects
- possible out-of pocket expenses
- concerns for loss of medical coverage or care
- concerns over loss of income.

These factors can be addressed with a mindful clinical trial design and communication. Lived experience advocates can help researchers to overcome these barriers through the design of the trial.

Specific design advice

There are many aspects of designing a research study from basic research to clinical implementation studies. Each study has different considerations. Research advocates don't need to be experts on clinical trial study design but it is important to understand where your input can aid in the design process.

Here are some areas where engagement between those with SCI lived experience and researchers can help in the design of clinical trials:

- Evaluation of risk and benefits of the intervention
- How best to explain the elements of the research and communicate the information in lay language

- Understanding the most relevant outcomes for the SCI population and leveraging real-world evidence
- Identify ways to maximize adherence to the trial protocol elements
- Identifying and reducing the burdens of participation
- Understanding potential concerns of trial candidates and making it easier to participate

These are some of the ways that SCI research advocates can help to reduce the challenges of participating in clinical trials. Another aspect of this is to advise from personal experience as well as the community preferences.

Understanding the community

SCI research advocates can provide a unique perspective drawing from their own lived experience along with an understanding of the broader community needs. Effective advocates can speak to the functional preferences of the SCI community as well as to their own personal life experiences. This is why it is important to be knowledgeable about the results of community preference studies that included people living with SCI.

There are published SCI preference studies over the course of two decades with the most recent published in 2022. Overall the following are the top 7 referenced preferences:

- Bladder & Bowel
- Hand Function
- Walking
- Sexual Function
- Pain
- Trunk/Balance
- Sensation

Taking these functional preferences in mind, research advocates can communicate how these preferences related to spinal cord injury impact everyday life, such as activities of daily living, quality of life, and overall health and wellness.

The National Spinal Cord Injury Statistics Center at the University of Alabama Birmingham publishes facts and figures about spinal cord injury on an annual basis. These statistics are gathered from participating SCI Model Care Centers in the U.S. and provide a sampling of the demographics, costs and more. This is a sampling of the community that can be supplemented with other published studies. It is most important for research advocates to be aware of this information in their roles as research advisors.

Participating in a clinical trial places a large burden on a study participant and their caregivers. It can be more logistically difficult if the study requires travel. It can interfere with daily life,

employment, relationships and social activities. It also can increase financial costs, even though the treatment costs are covered by the trial sponsor.

Loa Hornung – It's a lot of work on the caregiver's part and on the participant's part, um, we had to do some, a lot of things at home, uh, that weren't just been able to do at, um, the facility when he was there. It takes a lot of dedication and time, not only at home, but the driving back and forth and the time that he has spent in there. At times, he was in there for six to seven hours a day, um, doing different assessments, um, and being part of the research. So really the main difficult thing for us is just been, uh, time consuming, uh, a lot more work. Spinal cord injury is a lot of work in itself. Um, once we joined research, uh, it gave us a little bit more added work, uh, but we were able to with time, uh, adapt well.

John Chernesky – Think back to, to one I participated in, uh, a few years back, and it was not in my own home city. It was, uh, a few hours away. Um, and it was a requirement that I'd be there from Monday to Friday. Um, and so that meant traveling a few hours every Monday morning and every Friday afternoon, uh, being away from my family, uh, and my friends. Um, and at the same time trying to maintain my employment and work remotely whilst traveling many hours per day. And then on top of that, there's this added cost because now I'm away from home, so I have to pay for an Airbnb or a hotel plus mileage, plus all the wear and tear on my vehicle. So, you know, there's a lot of added costs beyond just the financial ones. There's the, the social impact and, and just the, the plain exhaustion of, of traveling back and forth constantly, which, uh, I was not expecting it to be such a, a major, uh, barrier.

Research advocates can help clinical trial sponsors understand what it takes for someone with an SCI to participate in a study.

John Chernesky – A lot of trials are designed by researchers in isolation, and oftentimes they've never participated in a clinical trial previously. Um, and really don't fully understand the impact of not just the intervention and what it does to the individual and another body, but, you know, continually having to go in multiple times per week with all the various hurdles you need to cover with transportation and living your life and managing a spinal cord injury.

Ian Burkhart – There are a few things that I shared with the trial organizers while I was a part of, uh, the, the few trials that I had been enrolled in, um, mainly surrounding, you know, what it was like from my personal experience, um, to participate in, you know, what the, what all entailed for me. You know, getting to the trial site, the accessibility of the location, and you know, as well as how I, I felt, you know, outside of the trial experience, um, because those weren't questions that they, they're capturing directly, um, within the research that they were doing. But I think it can help further improve their future research.

Advocates and researchers can work together to identify barriers and develop solutions to them.

John Chernesky – One of the big challenges in conducting clinical trials is compliance and retention of participants. And if you design a trial that has minimal barriers to participation, people are likely to comply with the intervention a lot better and likely to continue right through to the completion of the trial.

There's this excessive burden that's often added if there's far too many assessments, um, and testings that go on throughout the trial. So I often find that the more successful clinical trials are the ones that group those, um, assessments on singular days. So instead of perhaps doing, uh, assessments on a daily or weekly, uh, frequency that they, they group them together, maybe, uh, beginning, middle, and end of intervention, um, and not have an excessive amount of time needed to conduct these assessments.

Things like travel and accommodation costs for participants being included in their budgets, um, is gonna really make it more attractive to people and reduce that burden on their individual, on, on the individual.

Ian Burkhart – I did have a period where, um, I did not have my vehicle, it was in the shop, and the trial organizers were able to help arrange transfer transportation for me to get to and from the clinical research site, and that definitely made it easier so we didn't have to stop the research for that period of time.

SCI research advocates also can help research teams communicate the requirements of a study, expectations of participants, and decisions about whether people are accepted into enrollment, all of which can encourage future participation.

Rob Wudlick – Communication with your participants and empathy are, um, really important. This trial that I wanted to participate in years ago I had flown cross country to do the screening. They were very positive with me. Uh, it seemed like I had passed the screening and they were excited to enroll me. And then it kind of just went radio silent for a few months. Christmas Eve they reached out, or the lab, uh, there was a graduate research assistant and she reached out and basically told me that, uh, I wasn't going to be in the study. And I mean, it would've made a huge difference in my life participating in it potentially. And so it was really a let down.

Additionally, communicating the results of completed studies in lay language for the SCI community to understand, is an essential step where research advocates can play an important role.

Sharing results lets people know that their participation mattered and encourages future participation in other studies. Even when studies fail, participants want to know what happened, and what was learned. Research advocates can help communicate results in ways that participants will understand.